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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,322	01/15/2002	Wencai Ye	1624-0132P	7072

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EXAMINER
KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
1623	7

DATE MAILED: 11/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,322	YE ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-14 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms, which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are:

1. Page 4: line 1, the term "diabetic" should be changed to "diabetes". Line 3, the term "officinal" should be changed to "pharmaceutical". Line 25, the terms "elute as" should be removed and the terms "as eluant" should be inserted before the term "obtaining". In line 27 also the terms "elute as" should be removed and the terms "as eluant" should be inserted before the term "obtaining". In lines 25 and 27, it should be stated if the ratios are volume: volume. In line 27 the term "methanol" is misspelled.

2. Page 5: paragraph 5 starting with the sentence, " which includes administrating prophylactic or treatment effective quantity of Gymnemic acid derivative.... To the patient suffered from diseases" does not read well. It should be restated clearly.

3. Page 7; the last two lines as stated are not clear.

4. Page 8: The text on the entire page as written is not clear. In the structure where two carbohydrate units are joined together, it appears that the numbering on the structure is inverted. For example, in the structure what is supposed to be 6" appears as "9.

5. Page 9: lines 1-3 are not clear as stated. Lines 23-24, states frozen dry powder for injection. It is not clear what this means. Frozen dry powders are not known to be used in injections.

6. Page 10: line 2, the term "disintegrating" is misspelled. In line 3, it should be "diluting agent". In line 7, at the end, it should be "magnesium stearate". The sentence "According to this invention, the or pharmaceutical base said formula I Gymnemic acid derivative can be prepared as follows:" should be rewritten to convey clearly what is meant. At the end of the step labeled a) the recitation "until there was no methanol, for use" is not clear.

7. Page 11, line 1, the terms "elute as mixture" should be removed and the terms "as eluant" should be inserted after the numeral 40. Also, for the ratio it should be indicated if it is volume-to-volume or weight-to-weight or as appropriate. The steps starting at line 3 are not labeled in the proper alphabetical order. In the steps labeled a) and d), at the end of the sentence, it is not clear what is meant by ready for use. If it is ready to carried over to the next step it is not necessary to state so. If it is ready for use for some other purpose, then the purpose should be stated. The step labeled c) is not clear. The entire step c) has to be rewritten to convey clearly what is being performed in that step. The term "mixing the dry extracts in step b) with raw silica gel" is recited. It is not clear what this means. It is also recited further in the same sentence "thin layer chromatography of silica gel H". This is also not clear. It should be stated "chromatography on silica gel". It is not clear what the H after the term gel stands for. Usually, the grade of silica gel is expressed as mesh size. Overall, in step c) according to the way it is written, it appears that two chromatographic separations are performed, the first on silica gel and the second on C_{18} column. It is recited that the initial separation is done via thin layer chromatography on silica gel.

Separations are usually not done via thin layer chromatography. It is usually done by column chromatography or by preparative thin layer chromatography. This fact needs to be stated clearly in step c). Also in the same sentence the term "methanol" is misspelled.

8. Page 12: Example 1: The paragraph beginning with the terms "1000g raw powder" and ending with "were obtained" does not read well and is not clear. The whole paragraph has to be rewritten stating clearly the process of preparation. The last two lines on page 12 states "The physics and chemistry data". This should be corrected to read, "The physical and spectral data for Compound A and Compound B are given below:".

9. Page 15: In Table 2, the title "Carbon atom of C-3" is confusing and also misleading. The left column also mentions glutamic acid 1 through glutamic acid 6. The saccharide part in compounds A and B are not glutamic acid. It is not clear which carbon atom in the saccharide part for which the chemical shift is provided. The terms glutamic acid 1 through glutamic acid 6 appearing on the left column is also confusing. The word "Saccharide" appearing on top of table 2 is misspelled. More space should be given between the text and the structures on this page.

10. Page 19: Table 4, Left column, middle of the page, the term C-28 appears and the rest of the cells on the right are blank. It is not clear if C-28 is a title for the data appearing below it. Even if it is a title, it is not clear what C-28 means. Also the entries glc1, glc2, etc. on the left column are confusing. It is not clear if the numerals appearing after the entry "glc" refers to the carbon atom on the glucose or if the numeral refers to the carbohydrate moiety as a whole.

These are some of the errors that appear in the specification which are either confusing or not clear. It is the applicant's responsibility to check the entire specification and correct these and other such errors that appear throughout the specification.

Claim Rejections - 35 USC § 101

Claim 12 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is not clear. It appears that in Claim 1, line 6, in the recitation "R_3 is H, and R_2 symbolizes the following radical, or" the term "or" after the term "radical" seems to be in the wrong place and is confusing. Looks like the term "or" should be before the terms "R_3 symbolizes" in the last line on page 28. Clarification is needed.

In Claims 2-7 the term "derivatives" should be changed to "derivative" since only one derivative is being claimed in all of these claims.

Claims 3-7 fail to end with a period. In the absence of the period it is not clear where applicant intends for the subject matter claimed to conclude additional text if any.

In Claims 8 and 9 "a" should be inserted in front of the term "pharmaceutical" and "an" should be inserted in front of the term "excipient", unless more than one carrier or excipient is included in the composition. In Claim 9 the recitation, "for the prevention or treatment of the diseases associated with hyperglycemia, hyperlipidemia and platelets aggregation" does not add any patentable weight to the claim and should be removed.

Claim 10 recites the limitation "composition" in Claim 1. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite a composition. The terms "contents" should be replaced with the term "amount". Line 4 of the claim recites compounds A, B, C, D, E, but towards the end of the claim the percentage for a compound F is recited. The letter "F" is missing in line 4, if there is a compound "F" in the composition. Also it is not clear what compounds A through F are. Either these compounds should be identified by a structure or a chemical name in the claim or they should be identified clearly in Claim 1, even though they are described in the specification. Also, claim 10 as recited, is seen as a duplicate of claim 14 except for the dependency.

The term "An" is missing at the beginning of Claim 11.

Claim 12 provides for the use of Gymnemic acid derivatives of the formula I and II, but, since the claim does not set forth any steps involved in the method/process of use, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

In Claim 13, the steps recited are not listed in the proper alphabetical order. The steps labeled c) and d) appear twice. The first two steps recited should be labeled a) and b) respectively. In the first occurrence of Claim 13(d) as recited, the term "a" is missing in front of

the term "ointment". It is not clear what the term "ointment" means and is confusing in the context in which it is used in the claim. The term ointment generally is used to mean a semi solid preparation applied as an external medicament. In the second occurrence of claim 13(c) as recited, the terms "elute as" should be removed and the terms "as eluant" should be recited after the numeral 40. Also, it should be stated clearly if the ratios recited for chloroform and methanol is volume: volume or weight: weight, or as appropriate. In the second occurrence of claim 13(d) as recited, the parenthesis should be removed. If the numerals 20/80-40/60 refer to the ratios of methanol and water it should be indicated if the ratios are volume : volume or weight : weight, or as appropriate. The terms "elute as" should be removed and the terms "as eluant" should be inserted before the term "Gymnemic". The term "methanol" is misspelled in the second occurrence of Claim 13(d).

Claim 14 recites the limitation "composition" in Claim 2. There is insufficient antecedent basis for this limitation in the claim. Claim 2 does not recite a composition. The terms "contents" should be replaced with the term "amount". Line 4 of the claim recites compounds A, B, C, D, E, but towards the end of the claim the percentage for a compound F is recited. The letter "F" is missing in line 4 if there is a compound "F" in the composition. Also it is not clear what compounds A through F are. Either these compounds should be identified by a structure or a chemical name in the claim or they should be identified clearly in Claim 1, even though they are described in the specification. Also, claim 14, as recited, is seen as a duplicate of claim 10 except for the dependency.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 703-305-4837. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

GK
November 11, 2002